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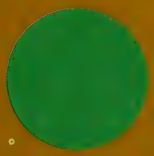
Quality of Medical Care Assessment Using Outcome Measures



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U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
Health Resources Administration

National Center for Health Services Research Research Summary Series

The *Research Summary Series* is published by the National Center for Health Services Research (NCHSR) to provide rapid access to significant results of NCHSR-supported research projects. The series presents executive summaries prepared by the investigators at the completion of the project. Specific findings are highlighted in a more concise form than in the final report. The *Research Summary Series* is intended for health services administrators, planners, and other research users who require recent findings relevant to immediate problems in health services.

Abstract

This is a summary of a two-volume final report of a contract to develop measures of short-term outcome for eight common health problems. The first volume is a conceptual overview of the role of outcome information in quality assessment, including an extensive annotated bibliography. The second volume describes the epidemiology of each condition chosen for study and the results of an expert panel meeting at which disease-specific outcome measures were developed. The eight problems covered are asthma; breast mass and breast cancer; cholecystectomy; diarrhea and dehydration in children; ischemic heart disease; osteoarthrosis; otitis media in children; and tonsillectomy with or without adenoidectomy. Summary tables of the measures suggested for each condition are included in each chapter. Also included are measures of risk factors which would have to be controlled in order to adjust for patient mix differences in interpretation of group outcomes.

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This *NCHSR Research Summary,* written by Robert H. Brook and Allyson Davies Avery, describes work by The Rand Corporation, Santa Monica, CA 90406. The work was performed for NCHSR under contract HRA 230-75-0112.

The two-volume final report summarized here is available from the National Technical Information Service, Springfield, VA 22161 (tel.: 703/557-4650) (both in paper and in microfiche), order numbers PB 258 613 and PB 258 614. The first volume is *Quality of Medical Care Assessment Using Outcome Measures: An Overview of the Method,* published as a supplement to *Medical Care,* 15, no. 9, September 1977. The authors are R.H. Brook, A.D. Avery, S. Greenfield, L.J. Harris, T. Lelah, N.E. Solomon, and J.E. Ware, Jr. The second volume is *Quality of Medical Care Assessment Using Outcome Measures: Eight Disease-Specific Applications,* by A.D. Avery, T. Lelah, N.E. Solomon, L.J. Harris, R.H. Brook, S. Greenfield, J.E. Ware, Jr., and C.H. Avery.

Robert H. Brook is the author of an earlier NCHSR report on the same subject, *Quality of Care Assessment: A Comparison of Five Methods of Peer Review,* published in 1972 while he was an NCHSR staff member.

Additional copies of this summary may be obtained on request from the NCHSR Office of Scientific and Technical Information, 3700 East-West Hwy., room 7-44, Hyattsville, MD 20782 (tel.: 301/436-8970). Other current NCHSR publications are announced on the inside back cover.

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Foreword

One of the major tasks of health services research is to develop methods for monitoring the performance of the health care delivery system. A significant part of this effort is directed at the problem of measuring and assessing the quality of care.

While this research has a long history, most attempts to measure quality have focused either on the structure or the process of care, and not on health outcomes. This tendency partly reflected the difficulty of measuring outcome. It also reflected a general view that improved health care would lead to better health, and that the way to better care was the infusion of more resources. The prevailing mentality was, "When in doubt, do it."

Recently, public policy has taken a new direction. Concerns about rising costs, combined with an increasing awareness of the limitations of devoting more resources to health care in order to achieve better health, have given rise to policies directed at restricting the use of resources. The current emphasis on cost containment represents a radical move away from the old perspective, and puts the burden of proof on those who would provide more and costlier services. The new rule is becoming, "When in doubt, leave it out." This change demands new ways of measuring and assessing the quality of medical care services.

What is required is a marked improvement in our ability to relate the use of health services, and the resources they require, to health outcomes. To be most effective, expenditure limiting strategies should be directed at amenity and not necessity. Although the distinction between the two has been elusive, the effect of different therapeutic processes on outcomes will be the central concern both in the implementation of cost containment policies and in the assessment of their effectiveness.

The study presented here, supported by the National Center for Health Services Research, represents a significant step in addressing that issue. It provides a framework for the continuing development of outcome measures and offers several examples of both the feasibility

and applicability of this perspective. Particularly in light of the current policy climate, this is an important and timely advancement of the health services research effort.

Gerald Rosenthal, Ph.D.
Director,
National Center for Health Services Research
August 1977

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Preface

The purpose of the research was: (1) to prepare a conceptual paper that would place the outcome method for assessing quality of medical care in perspective, and (2) to develop disease-specific short-term outcome measures that could be used to evaluate the quality of the medical and/or surgical care delivered to patients with one of eight different disease conditions or surgical procedures.

The first volume of the final report (PB 258 613) presents an overview of the outcome method of assessing the quality of care, with reference to theoretical issues and to the way in which the method has been employed in previous quality of care research. The report details the specific approach taken to develop outcome criteria for eight disease conditions, and presents the outcome standards that are of highest priority for use in assessing quality of care delivered to patients with the conditions studied. The volume concludes with a series of observations as to the feasibility of the outcome method in general, and as applied to this research, and offers suggestions for further developmental research on methods of quality assessment.

The second volume (PB 258 614) contains technical chapters on each of the eight conditions and procedures studied: asthma in children and adults; breast mass and breast cancer; cholecystectomy; diarrhea and dehydration in children; ischemic heart disease (including angina pectoris, myocardial infarction, and sudden death); osteoarthrosis; otitis media in children; and tonsillectomy with and without adenoidectomy. Included are the outcome criteria and standards proposed for use in measuring the quality of care delivered to patients with these conditions.

This NCHSR Research Summary gives a brief executive summary of the conceptual discussion included in the first volume, along with a description of the specific method used and an illustration of the types of outcome and standards developed.

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Introduction

The quality of personal medical care services is a matter of increasing public concern. Major efforts are under way to increase the quality of medical care services through establishment of ongoing quality assurance mechanisms. However, these efforts are hampered by lag in development of adequately tested methods for quality assessment.

Quality of care assessments deal with one or more of the three following measures of medical care: structure, process, or outcome. Most of these are based on the common assumption that adequate resources (structure) contribute to adequate diagnostic workups and treatment (process), which in turn result in favorable health (outcome).

Within this conceptual framework, many studies have focused on developing and testing ways to measure the adequacy and quality of the process of medical care. There is, however, a major problem with measurement of quality through use of process indicators alone: the relationship between the medical care process itself and health status is not always direct. In many cases, it may be so confounded by intervening variables, such as patient compliance, that adequate process may not result in good outcomes. On the other hand, apparently poor process may result in good outcomes if the process criteria selected are invalid or are incorrectly measured. Thus, the validity of using process measures alone as indicators of the quality of medical care has been questioned. Several studies also demonstrate little relationship between quality assessments made using structural measures and those using process measures. These statements about process and structural measures, however, must be qualified. Relationships among structural, process, and outcome measures in a quality assessment may become more apparent and the use of structural and process measures in assessing quality more appropriate when these terms are defined and conceptualized more precisely and when they are measured more reliably.

In contrast, the face validity of outcome assessment is more apparent, since measurement of outcome necessitates measurement of "health" itself, or some aspect of it. However, when outcome measures have been proposed for use or applied to evaluate quality of care, several problems have arisen:

1. The outcomes most frequently used, such as death or incidence of major complications, may be so uncommon that detection of sig-

nificant differences between patient groups requires samples so large that the feasibility of the study is limited.

2. "Ultimate" outcomes, such as death and restoration of normal function, often occur so late in the course of treatment that timely evaluation is impossible.
3. Such commonly used measures as disability and return to function are heavily influenced by intervening factors, such as genetic makeup and physical and social environment, that are beyond control of the medical care system proper.
4. Information about many outcomes is not readily available, requiring follow-up interviews. These are expensive to conduct and difficult to complete for a high proportion of the relevant patient population.
5. Information is lacking on the breadth of the outcome criteria that should be used in assessing quality of care. Should outcome assessment be limited to physical and physiologic measures, or should it include psychological measures such as sexual function following a radical mastectomy for breast cancer?

The problems enumerated above lead at least to questions about the feasibility, reliability, and validity, of the outcome method in assessing quality of care. As if these problems were not enough, there are currently no outcome criteria and standards available for use by operational quality assurance programs. Despite this fact, the outcome method is being promoted heavily. There is a legal mandate for medical care evaluation studies to be performed under the auspices of Professional Standards Review Organizations in all hospitals with Medicare or Medicaid patients. The Bureau of Quality Assurance, the agency in the Department of Health, Education, and Welfare responsible for implementing the program, encourages use of outcome assessment whenever possible in these evaluations. The Joint Commission on the Accreditation of Hospitals, a voluntary nongovernmental agency, has developed a Performance Evaluation Procedure that must be implemented by hospitals in order to be reaccredited. The procedure depends heavily on assessment of appropriate patient outcomes. Finally, the Health Maintenance Organization (HMO) Act of 1973 established a second federally mandated quality assurance system. The law requires implementation of quality assurance systems in all federally supported HMOs to assess the quality of care using outcome measures that reflect both provider and consumer values. In summary, there exists a paradoxical situation, in which policy demands that operational quality assurance systems use the outcome method to assess quality of care, while there is a dearth of valid and reliable outcome criteria and standards and no method of proven feasibility by which they can be applied.

In an attempt to address some of these problems and further the state of the art of quality assessment using the outcome method, the National Center for Health Services Research contracted with The Rand Corporation to prepare a conceptual overview of the outcome

method and to develop "proximate" (short-term) outcome measures for use in assessing the quality of care delivered to patients with any one of eight different disease conditions.

This research was limited by the scope of the contract insofar as it was viewed as a first phase or developmental effort. Thus, many conceptual problems were not addressed in the technical work done to develop outcome criteria and standards. In particular, two major limitations were placed on the research. It was not possible to collect new data to test the validity of the outcome criteria and standards established. Moreover, disease-specific process criteria were not developed simultaneously, thereby negating comparison at this time of the validity of process and outcome approaches to assessing quality of care.

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Conceptual overview: the outcome method of quality assessment

The ways in which outcome information can be used to assess quality of medical care can be summarized as follows:

1. To monitor prospectively the quality of care provided by groups of physicians or by individual providers as it is delivered, in order both to arrive at a value judgment about quality and to intervene and change the care process when necessary to avoid adverse outcomes; and
2. To monitor retrospectively the quality of care, for one of two purposes:
   a. within a physician's office or a single delivery system, to identify problems in health outcomes that result from inappropriate or inadequate processes of care and to change these processes to achieve closer-to-optimal outcomes; or
   b. to do a comparative evaluation of different aspects of a delivery system (whether a single system or a local, regional, or national system) in order to make value statements that will support policy decisions.

Prospective monitoring for quality of care assessment

While prospective monitoring of outcomes is used by every physician to check patient progress, no examples could be found in the literature of the use of outcomes for the dual purposes of noting clinical progress and assessing quality. Increasing availability of populations of known size associated with specific medical care delivery systems (e.g., group practices and HMOs) may make possible the use of such techniques. Professional Standards Review Organizations might also use prospective monitoring techniques in performing medical care evaluation studies.

Retrospective monitoring for quality of care assessment

In-house quality assessment. Retrospective monitoring of the quality of care is generally undertaken with one of two purposes in mind. The first is to identify and correct major deficiencies in quality of care. Such a study is usually designed for use in changing practice behavior in an identifiable medical care delivery system, such as a hospital, clinic, or solo or group practice. Results are not intended for publication, and comparisons with other systems are not made.

Considerable effort has been spent on developing quality of care assessment methods that use outcome information for this purpose. Despite the developmental work, none of the approaches has been rigorously evaluated as to its ability to maximize the health status of patients in the medical care sites or systems that have instituted such quality assurance activities. At present, it is perhaps fair to say that quality assurance activities based on outcome information have contributed little to improvements in health.

Outcome assessment for policymaking. The second purpose to which retrospective monitoring of quality of care via outcomes can be put is comparative evaluation of different aspects of a delivery system, the results of which are intended to support policy decisions. While policy-relevant quality assessment sponsored by the federal government is a major example of this use of outcome information, it can also be undertaken at a regional level or within a self-contained delivery system with multiple components and responsibility for efficiently allocating resources between them.

Control for factors outside the influence of medical care

While their purposes are dissimilar, both in-house monitoring and policymaking use the outcome method in essentially the same way. Only one distinction must be made: the stringency with which the effects on outcomes of factors outside the influence of the medical care system are controlled when outcome data are analyzed. Depending on the purpose, some type of control is necessary in order to conclude that differences in outcome are attributable to differences in quality of care delivered, rather than to differences in patient- or disease-related factors that cannot be altered by the medical care system.

Methods of control must be far more stringent when retrospective monitoring is undertaken for policy-relevant quality assessment studies than for in-house studies. This is necessary because the major product of the policy-relevant study is detection of moderate differences in quality between system characteristics of concern and development of policies that will reduce or eliminate such differences. In contrast, in-house assessment is undertaken to identify major deficiencies in care, which the method itself is sensitive enough to detect without rigorous controls.

Approaches to development of outcome criteria and standards

Once the outcome method has been chosen as appropriate for quality assessment, the disease condition for study must be selected, outcome criteria identified, and standards of care set. Outcomes are then measured, and a value judgment made as to whether care is of good or poor quality in relation to the standards established. There are several approaches to each of these tasks. Many different criteria are available to guide the selection of disease conditions, such as, the out-

come criteria selected can be either specific concepts (such as mortality or functional status) or a global concept of "overall health status"; the criteria chosen can represent one or multiple dimensions of health; standards can be implicit or explicit; several different points in time can be used for measurement of the outcome; and different approaches can be taken to evaluating the results of the quality assessment. Each of these topics is dealt with in turn in the first volume of the report, both from a theoretical point of view and with reference to the approaches used in quality of care studies that have relied on the outcome method and are reported in the literature. (An extensive literature review, in tabular form, is appended to that volume.) Problems that may be encountered in criteria selection and standard setting with both uses of the outcome method are chiefly due to lack of information and guidelines in clinical and health services research literature, and are reviewed in some detail.

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Development of short-term disease-specific outcome measures

Outcome criteria and standards were developed for eight conditions and surgical procedures: asthma in children and adults; breast mass and breast cancer; cholecystectomy; diarrhea and dehydration in children; ischemic heart disease (including angina pectoris, myocardial infarction, and sudden death); osteoarthrosis; otitis media in children; and tonsillectomy with or without adenoidectomy. These conditions and procedures represent a mix of medical and surgical, inpatient and outpatient, emergency and nonemergency, and adult and pediatric problems (see Tables 1 and 2). This mix was chosen in order to explore the feasibility of developing outcome measures across different areas of medical specialty, locations of care (ambulatory versus inpatient), and patient age groups. A major factor affecting this selection was the extent to which intervention of medical care has an impact on the natural history of the disease. In identifying conditions for study, those for which medical care has a considerable impact on psychosocial dimensions were included to test adequately the utility of the outcome method in assessing quality of care. The other major factor guiding choice of conditions was the frequency with which they occur in the general population. Two other criteria—knowledge of nonmedical factors affecting the natural history of the condition, and availability of well-defined treatment modalities for the condition—were given less weight in selecting these eight conditions and procedures. Health problems (i.e., diarrhea, breast mass, osteoarthrosis, and ischemic heart disease) were included deliberately; the majority of patient contacts with medical care are for symptoms, signs, or problems, and the feasibility of developing outcomes for these as well as for specific diagnoses must be attempted before the utility of the method is completely determined.

The outcome standards developed during this research are explicit, disease-specific, and designed for measurement within one year of the intervention of medical care. The criteria to which these standards pertain were drawn from a cluster of different dimensions of health. The generic categories included physical, physiologic, and psychosocial outcomes that are affected, positively or negatively, both by the disease process and by the treatment process. These standards were developed by panels of physicians representing a variety of medical and surgical specialties, geographic areas, types of medical care or-

Table 1: Study Conditions Classified By Medical Care Problem Area

	Inpatient	*Ambulatory*	*Medical*	*Surgical*	*Nonemergency*	*Emergency*
Inpatient	Asthma Breast mass/ cancer Cholecystectomy Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media Tonsillectomy	Asthma Breast mass/ cancer Diarrhea and dehydration Otitis media	Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease	Breast mass/cancer Cholecystectomy Tonsillectomy	Asthma Breast mass/ cancer Cholecystectomy Diarrhea and dehydration Ischemic heart disease Tonsillectomy	Asthma Ischemic heart disease Diarrhea and dehydration
Ambulatory		Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media	Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media	Breast mass/ cancer Otitis media	Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease Otitis media Osteoarthrosis	Asthma Diarrhea and dehydration Ischemic heart disease
Medical			Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media	Breast mass/ cancer Ischemic heart disease Otitis media Osteoarthrosis	Asthma Breast mass/ cancer Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media	Asthma Ischemic heart disease Diarrhea and dehydration

Surgical	Breast mass/ cancer Cholecystectomy Ischemic heart disease Osteoarthrosis Otitis media Tonsillectomy	Breast mass/ cancer Cholecystectomy Ischemic heart disease Osteoarthrosis Otitis media Tonsillectomy	
Nonemergency		Asthma Breast mass/ cancer Cholecystectomy Diarrhea and dehydration Ischemic heart disease Osteoarthrosis Otitis media Tonsillectomy	Asthma Diarrhea and dehydration Ischemic heart disease
Emergency			Asthma Diarrhea and dehydration Ischemic heart disease

Table 2: Study Conditions Classified by Age and Sex [a]

Age and Sex Group	Condition							
	Asthma	*Breast Mass/ Cancer*	*Cholecystectomy*	*Diarrhea and Dehydration*	*Ischemic Heart Disease*	*Osteoarthrosis*	*Otitis Media*	*Tonsillectomy/ Adenoidectomy*
Female								
<15	+			[d]			+[g]	+
15–29	+	+[c]	+					
30–44	+[b]	+	+		+[e]	+		
45–64	+	+	+		+	+[f]		
65+		+	+		+	+		
Male								
<15	+			[d]			+[g]	+
15–29	+							
30–44	+		+		+			
45–64	+[b]		+		+	+[f]		
65+			+		+	+[f]		

[a] Table entries indicate age and sex groups for which outcome standards were developed during the research.
[b] Through 55 only
[c] 20 and above only
[d] 1–24 months only
[e] 40–75 only
[f] 50–80 only
[g] 0–16

ganizations, and both the academic and practicing physician communities.

These standards are designed for use in retrospective monitoring of the quality of care, particularly when it is undertaken to support policy decisions. Care was therefore taken to identify all factors outside the influence of medical care that might adversely affect outcomes and to propose methods that would control for this effect when analyzing data on outcome and comparing different patient groups or delivery systems. The standards are also appropriate for in-house peer review systems; when they are applied for that purpose, the control techniques will not have to be as rigorous as those proposed. Table 3 presents the top-priority outcome criterion and standard for each of the eight topics studied (see complete standards).

Method of setting standards

Extensive literature reviews were prepared by project staff for each of the conditions or procedures selected. The purpose of these reviews was to provide background materials necessary to enable expert panels to identify criteria and develop outcome standards for the conditions and procedures studied. The panel meetings were a focal point of the research design. Every effort was made to include the following experts on each panel: a board-certified physician who had done significant research on the condition using process and/or outcome measures; a board-certified physician in private practice who was expert in treating the condition in a community setting; and a board-certified physician-epidemiologist, or a physician who had done significant research on the condition from that perspective. Achieving this breadth on each panel was considered important in assuring that the resulting outcome standards would reflect an aggregate of opinions and experience and would be generally acceptable to physicians across the country.

Panel meetings were chaired by one of the three project staff physicians, each of whom assumed responsibility for two to four of the conditions or procedures selected. After critiquing the scope and content of the literature reviews, the panels addressed themselves to five tasks in development of outcome criteria and standards: (1) operational definition of the disease condition or procedure and relevant patient population; (2) identification of those factors outside the influence of medical care that could adversely affect outcomes and that must be controlled for in analyzing outcome data; (3) identification of outcome concepts appropriate for measurement in quality assessment, in terms of sensitivity to variations in the quality of care provided; (4) standard setting; and (5) identification of the points in time at which the outcome should be measured. In developing standards, the panels attempted to estimate on the basis of the literature and their own experience the proportions of patients who might be expected to have a specified status on a given outcome criterion if they had received care

Table 3: Top-Priority Outcome Standards

Outcome Concept	*Time Window*	*Data Source*	*Factors Outside Influence of Medical Care*	*Standard*
			ASTHMA	
Changes in disease severity	One year	Patient/parent interview Medical record	Age Sex Race Socioeconomic status Environmental factors Disease severity	Given optimal quality of care, 98 percent of all asthmatics classified as Stage A, B, C, D, or E should not have progressed to a more severe stage. Given optimal quality of care, the percentage of the asthmatic population that should be classified in each stage at any point in time is as follows: Stage — Percent of Population A — 50 B — 25 C — 15 D — 10 E — <1 If the percentages of asthmatic patients classified in Stages C–E are more than those listed above, then optimal care is not being rendered.

BREAST MASS-BREAST CANCER				
Nodal status (breast cancer)	At time of initial treatment	Medical record Hospital discharge abstract Pathology report Patient interview Tumor registry	Age Tumor histology	60 to 70% of women should have negative nodes on histologic examination at the time of initial treatment.
CHOLECYSTECTOMY				
Mortality	At discharge 40 days post-operatively	Medical record Hospital discharge abstract Patient (family) contact	Age Sex Socioeconomic status Disease severity Common bile duct exploration Physical status Presence of comorbid condition	Mortality rate: 0.8% for cholecystectomy alone 1.1% for cholecystectomy and *negative* common bile duct exploration 2.6% for cholecystectomy and *positive* common bile duct exploration *All deaths following cholecystectomy should be investigated as to process of care.*
DIARRHEA AND DEHYDRATION				
Mortality	End of illness episode	Medical record Hospital discharge abstract Death certificate Vital statistics Parent interview	Severity of disease at time of admission to hospital or on first medical care contact Age of patient: under one month; one month to two years	*No deaths should occur, regardless of disease severity, in any children aged birth to two years.*

Table 3: Continued

Outcome Concept	*Time Window*	*Data Source*	*Factors Outside Influence of Medical Care*	*Standard*
			ISCHEMIC HEART DISEASE	
Incidence of sudden death	Monitor annually	Medical record	None	*Average Quality Care* Using antiarrhythmic drugs and cardiopulmonary resuscitation, incidence of sudden death could be reduced by 2 to 3 percent. *Optimal Quality Care* Using antiarrhythmic drugs and cardiopulmonary resuscitation, incidence of sudden death could be reduced by about 10–20 percent.
			OSTEOARTHROSIS	
FUNCTIONAL CAPACITY: Mobility and daily living skills	Baseline: one month Outcome: one year	Patient interview/ questionnaire	Socioeconomic status Workmen's compensation (or litigation pending) Age Obesity Previous disease duration Joint involvement Extended care facility residence Disease severity at initiation of study Sex Race	Given optimal quality of care, no more than 10% of patients should decline in functional capacity during the year of care. 90% of patients should improve or remain the same in functional capacity if given optimal quality of care. Given adequate quality of care, no more than 20% of patients should decline in functional capacity during the year of care. 80% of patients are expected to improve or at least remain the same in level of functional capacity if given adequate quality of care.

				Any patient who has lost substantial mobility during the year of study, such that she/he becomes confined to a wheelchair or bed, should have received surgery. If the patient did not receive surgery, it may be indicative of poor quality of care. Such cases should be investigated.

OTITIS MEDIA

ILLNESS OUTCOMES: Hearing loss	Three, six, and 12 months after presentation for otitis media	Audiometric testing (tympanometry in children 0 to 3 years of age)	Risk group (I, II, III) Number of episodes of otitis media in previous year Age Sex Race Proximity to other children Allergy Season of year	Group I: Assuming optimal quality of care, no more than 20–25% of patients should have a hearing loss of 15–40 dB on any one of the test dates. Assuming optimal quality of care, no patients should have hearing loss of ⩾40 dB at any testing unless they are under specific care for this hearing loss. Assuming optimal quality of care, no patient should have a hearing loss of 15–40 dB on any two of these test dates unless they are under specific care for this hearing loss. (Standards were also developed for Risk Groups II and III, but are too lengthy to include in this table.)

Table 3: Continued

Outcome Concept	*Time Window*	*Data Source*	*Factors Outside Influence of Medical Care*	*Standard*
		TONSILLECTOMY AND/OR ADENOIDECTOMY		
APPROPRIATENESS OF SURGERY: Indications for surgery	At time of entry into study population	Medical record Hospital discharge abstract	None	Assuming optimal quality of care, *no* patients with contraindications for tonsillectomy, adenoidectomy, or tonsillectomy with adenoidectomy should have been operated on. 99% of medical records of patients undergoing tonsillectomy, adenoidectomy, or tonsillectomy with adenoidectomy should show evidence of normal PTT and PT values, platelet adequacy, and no family history of bloodclotting abnormalities prior to operation; records of black patients must additionally show evidence that presence/absence of sickle cell trait or disease was considered in giving anesthesia. Assuming optimal quality of care, the occurrence of tonsillectomy, adenoidectomy, or tonsillectomy with adenoidectomy among patients who have neither absolute nor reasonable indications for surgery (the "no indications" group) is an inappropriate use of the operation(s) and should be investigated as to the process of care.

of optimal quality during the illness episode or surgical procedure. In several cases, a standard indicative of average care was also developed. "Optimal" represents the professional opinion of what the best available care can achieve given present-day knowledge in medical, technological, and art-of-care areas; "average" suggests the typical care delivered by the average physician or community hospital.

The panels recognized that while certain factors outside the influence of medical care might adversely affect patient status on a given outcome measure, they might have no such effect on another. Thus, as outcome standards were developed, specific factors that should be controlled for when analyzing patient status on each outcome were identified. The panels also discussed techniques by which the effects of these factors could be controlled when analyzing outcome information. For several conditions (asthma, diarrhea, breast cancer), a variety of disease-specific classification systems that allow identification of subgroups of populations with similar prognoses were found in the literature. Two problems were encountered with these staging systems: (1) variables used to assign patients to stages were so poorly defined that use of the system would be impossible, e.g., many studies stratified patients in terms of "mild, moderate, and severe" disease, without providing further information to enable retrospective classification of other patients into such categories; and (2) with the possible exception of tumor staging systems, there are few widely accepted staging systems for any of the diseases. For several other conditions or procedures (cholecystectomy, ischemic heart disease), the panels proposed use of multivariate statistical techniques to control for factors not under the influence of medical care.

Each of the disease-specific chapters in the second volume of the final report contains summaries of the biomedical and health services research literature on each condition or procedure, the outcome criteria and standards developed by the panels, identification of the risk factors to be controlled for on each outcome measure, estimates of the size of the sampling frame necessary to identify samples of 200 patients with each condition, and lists of possible items that can be used in developing data collection instruments to measure outcome standards and control for external factors.

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Conclusions and recommendations

Quality assessment methods in general: conclusions

1. A major reason for focus on outcomes in assessing quality of care is the recognition that use of structural and/or process variables alone may be invalid, and the belief that outcome measures have more face validity in that they focus directly on health status. Use of outcome measures alone, however, may also produce misleading results.

2. Little is known about the congruence of the process and outcome methods of assessing quality of care, and about which has more validity as a basis for corrective actions and policy decisions.

3. Little is known about the comparative reliability of process or outcome methods done independently or in combination to assess quality of care.

4. The relative feasibility, particularly ease of access to and cost of necessary information, of both the process and outcome methods is not known.

Quality assessment methods in general: recommendations

1. Both the process and the outcome approaches require extensive testing as to their respective validities, reliabilities, and feasibilities.

2. The combined process-outcome approach also requires extensive testing as to its overall validity, reliability, and feasibility.

3. The respective methods should be tested for comparative validity, reliability, and feasibility, to determine which is the "best" approach to use depending on the purpose of quality assessment and the conditions selected for study.

Specific conclusions regarding this method

1. The approach used during this research to develop outcome criteria and standards for quality of care assessment was a successful one. For each of eight disease conditions or surgical procedures considered, expert panels were able to reach consensus and to develop outcome criteria and standards. These most basic conclusions are all the more important given the fact that most panel members had not been involved previously in similar tasks, nor had many of them ever examined the quality of care delivered to groups of patients.

2. A major reason for the success of the panel meetings was the extensive background work done by the project staff to identify issues

appropriate for developing outcome measures for each of the conditions and procedures, including lengthy literature reviews on each topic. Without such background information, it is doubtful that the panels could have reached agreement as readily or accomplished as much as they did during the panel meetings.

3. The tasks undertaken by the panels proved to be educational and stimulating for physicians and health-related professionals. Virtually all the panel members were intrigued by the issues of quality assessment using outcome information, and indicated considerable interest in participating in a second phase of study to test the reliability, validity, and feasibility of the outcome standards they developed. In addition, most suggested that the disease-specific chapters would be valuable contributions to the clinical literature and indicated that these papers, including standards, should be published.

4. The cost of this approach to developing outcome criteria and standards was approximately $25,000 to $30,000 for each disease condition and surgical procedure studied. These costs included panel honoraria, travel expenses, and considerable staff time spent in preparing background papers for panel meetings and in rewriting them to include the results of panel deliberations. If one percent of medical care expenditures is to be used for quality assurance activities, the cost of this activity represents 0.025 percent of such expenditures. If these papers can be used by many quality assurance systems, agencies, or programs as background information upon which to base a quality assurance program, then the costs seem justifiable. If, however, each organization doing quality assurance feels compelled to replicate this work, costs could become excessive.

5. Several problems were identified during the literature reviews and panel meetings that have important consequences for the use of outcome information in quality assessment. First, results of tests of the efficacy of medical processes and therapies reported in the literature usually represent those from the "best" clinical series. Absence of information as to what outcomes might result if average care were delivered to the population makes choice of appropriate outcome criteria and standards problematic. Second, few outcomes (generally physiologic and physical rather than psychosocial) are measured in efficacy studies. Absence of the use of a broad range of outcomes to establish the efficacy of medical care process makes selection of the "most important" outcome criteria for subsequent quality of care studies difficult. Third, much of the conventional clinical wisdom upon which choice of outcomes and points in time at which to measure them (time windows) might be based has not been documented in the literature, nor has the relative cost and benefit of monitoring outcomes traditionally selected by clinicians been examined. Fourth, neither the natural history of many common diseases nor the epidemiology of outcome events is well documented, making precise definition of disease conditions for study and choice of "time windows" difficult.

6. As a result of these problems, the outcome criteria and standards developed by the panels are not yet ready for use in ongoing quality assessment or assurance activities. The criteria and standards, as well as the "time windows" selected for measurement and the items pools proposed for use in data collection, must be subjected to rigorous pretesting and subsequent refinement prior to use.

7. Sample sizes for quality assessments based on the outcome criteria and standards developed for eight conditions and procedures will depend on several factors; most important is the frequency with which the given outcome occurs. Rough estimates suggest that the sampling frames necessary to identify samples of patients with these conditions may preclude outcome assessments focused on single practices or hospitals, unless the purpose is to identify physicians whose practice is so deficient as to be almost negligent, because the number of patients seen during a year will not be sufficient for statistical analysis. Instead, data will be aggregated across multiple practices or hospitals to identify requisite samples, and the resulting analyses of outcomes will focus on groups of physicians, a region, or a medical care area.

8. In order to identify patients for inclusion in quality assessment studies, implementation of this outcome method in any routine fashion will require development of record files that are diagnosis-procedure- and/or problem-specific for both ambulatory and inpatient care. For conditions that are generally encountered in ambulatory care and are described by signs and symptoms rather than specific diagnoses, uniform symptom codes are required. The uniform hospital discharge abstract now being introduced across the United States will prove valuable in identifying samples of patients for those diseases and procedures that require hospitalization.

Specific recommendations for further research using these outcome standards

1. Explicit, disease-specific process criteria and standards should be developed for each of the eight conditions and surgical procedures studied in this research.

2. After explicit process criteria and standards are established, data collection instruments that will allow assessment of both process and outcome of care should be developed for each condition and procedure.

3. Following development of data collection instruments, a decriptive quality assessment study of process and outcome of care for several patient groups in different settings should be undertaken. Such a study would test the reliability, validity, and feasibility of process and outcome criteria and standards, and of the "time windows" selected, and would determine the costs of conducting such a study. It is suggested that a subset of three or four of the eight conditions studied in this project be selected for testing during this phase.

4. It is expected that the descriptive pretest will lead to refinement

of criteria and standards and to development of reasonably valid and reliable data collection techniques. Once this has been accomplished, an experimental study should be undertaken to determine whether alterations in the quality of care actually improve health outcomes.

5. While the experimental study proceeds, value judgments must be made concerning the relative worth of achieved outcome improvements to determine whether the improvements in health outcomes are worth the cost. These value judgments could be obtained using the "willingness-to-pay" approach and should include the judgments of consumers and of patients who have had the particular disease or surgical procedure.

6. Research programs, as outlined in the preceding five recommendations, should begin on two conditions annually in order to provide the information necessary to determine the scope, benefit, and cost of quality assessment activities using this outcome method. The research cost would be about $250,000 per condition. While this work proceeds, work similar to that completed during the research reported in the first two volumes of this report should be done on eight to ten new conditions annually, at a cost of about $300,000 per year. Thus, funding of about $800,000 per year would be required to carry out such a research and development effort whose purpose was to extend the utility of the outcome method for quality assurance.

Policy recommendations

1. When studies on efficacy of medical care processes are funded, consideration should be given to designing them so that the results are directly useful in assessing quality of care. This would require the use of a broader range of outcome measures, including where appropriate the psychosocial aspects of care, and would require the determination of the benefit of a procedure or therapy when used under average as well as ideal circumstances.

2. Basic descriptive studies are needed to determine variations in monitoring of outcomes by individual physicians for the sole purpose of delivering medical care. These descriptive studies should be analyzed carefully and followed by experimental or quasi-experimental studies to determine the health effect of such variations. Such information could be used when outcome standards are developed for quality of care assessments.

3. If the approach taken during this research is to be followed, it will be necessary to update the reviews of the disease-specific literature every three to five years, depending on the condition and amount of relevant biomedical and health services research done in the intervening period. An ongoing mechanism to accomplish this updating and to disseminate results should be developed.

4. The report indicates the need to use a flexible approach in mandating use of specific outcome-oriented approaches in operational quality assessment programs. At this time, it is probable that the major

purpose of operational quality assessment programs is the identification of those physicians, practicing exceptionally poor medicine. This task could be accomplished by monitoring the process of care alone or perhaps, for surgeons, death rates from common surgical procedures. A more comprehensive system of quality assurance that will help all physicians to practice better medicine awaits answers to the fundamental questions addressed in this report. What tradeoff does the public desire between quality of life and length of life, if both cannot be maximized simultaneously owing to the nature of the disease? Who should set health outcome priorities: the public or the physician? How much is the public willing to pay either directly or indirectly for what level of health benefit? Answers to these questions would be easier to obtain if information covering the marginal effect on health of optimal versus average care were available. This information is not in the literature, and efforts to collect the data and make these decisions should be undertaken.

5. Two other uses for this outcome information were discussed in this report: (1) as dependent or control variables in studies that seek to address policy-relevant questions; and (2) as techniques by which physicians monitor the care of their individual patients. Information used in these ways serves a broad policy perspective or results in the monitoring of day-to-day care. Both uses could be improved remarkably if the influence of factors not under control of medical care on outcomes were better understood and if the complex relationship among these factors, the quality of care, and the cost of such care could be determined. This better understanding is conditional upon development of a research program addressing such issues.

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The following National Center for Health Services Research publications are of interest to the health community. Copies are available on request to NCHSR, Office of Scientific and Technical Information, 3700 East-West Highway, Room 7-44, Hyattsville, MD 20782 (tel.: 301/436-8970). Mail requests will be facilitated by enclosure of a self-adhesive mailing label. Note: Numbers in parentheses are order numbers for the National Technical Information Service, Springfield, VA 22161 (tel.: 703/557-4650).

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(HRA) 76-3136 The Program in Health Services Research (Revised 9/76)

(HRA) 77-3158 Summary of Grants and Contracts Active June 30, 1976

(HRA) 77-3167 Emergency Medical Services Systems Research Projects (Active as of June 30, 1976) (PB 264 407)

(HRA) 77-3179 Research on the Priority Issues of the National Center for Health Services Research, Grants and Contracts Active on June 30, 1976

(HRA) 77-3173 Summary of Recent Studies in Health Services Research, CY 1976 (in preparation)

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(HRA) 77-3161 Changes in the Costs of Treatment of Selected Illnesses, 1951-1964-1971 (HRP 0014598)

(HRA) 77-3163 Impact of State Certificate-of-Need Laws on Health Care Costs and Utilization (PB 264 352)

(HRA) 77-3164 An Evaluation of Physician Assistants in Diagnostic Radiology (PB 266 507)

(HRA) 77-3166 Foreign Medical Graduates: A Comparative Study of State Licensure Policies (PB 265 233)

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(HRA) 77-3152 How Lawyers Handle Medical Malpractice Cases (HRP 0014313)

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(HRA) 77-3165 Statutory Provisions for Binding Arbitration of Medical Malpractice Cases (PB 264 409)

(HRA) 77-3184 1960 and 1970 Hispanic Population of the Southwest by County (in preparation)

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(HRA) 76-3150 Intermountain Medical Malpractice Seminar

(HRA) 77-3154 Advances in Health Survey Research Methods

(HRA) 77-3181 NCHSR Research Conference Report on Consumer Self-Care in Health (in preparation)

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(HRA) 77-3162 Summary of Recent Studies in Health Services Research (PB 266 460)

(HRA) 77-3178 Algorithms to Train, Support, and Evaluate Paramedics (in preparation)

NCHSR Program Solicitations

(HRA) 77-3180 NCHSR Grant Solicitation: Health Services Policy Analysis Center

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16. Abstracts

This is a summary of a two-volume final report of a contract to develop measures of short-term outcome for eight common health problems. The first volume is a conceptual overview of the role of outcome information in quality assessment, including an extensive annotated bibliography. The second volume describes the epidemiology of each condition chosen for study and the results of an expert panel meeting at which disease-specific outcome measures were developed. The eight problems covered are asthma; breast mass and breast cancer; cholecystectomy; diarrhea and dehydration in children; ischemic heart disease; osteoarthrosis; otitis media in children; and tonsillectomy with or without adenoidectomy. Summary tables of the measures suggested for each condition are included in each chapter. Also included are measures of risk factors which would have to be controlled in order to adjust for patient mix differences in interpretation of group outcomes.

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